

Remarks

Claims 1-147 are pending in the present application. Claims 1-147 are rejected under 35 USC 112, first paragraph. Also, Claims 20, 22, 30, 50, 70 and 130 are rejected under 35 USC 112, second paragraph. In addition, Claims 1-2, 5-8, 20-23, 30-31, 34-37, 48, 50-51, 54-57, 68, 70-71, 74-77, 128, 130-131 and 134-137 are rejected for anticipation under 35 USC 102(a). Further, Claims 1-147 are rejected as obvious under 35 USC 103(a).

Additionally, the Examiner has objected to the abstract and to Claims 30, 50, 70 and 130.

The pending claims have been amended to further clarify the claims, to separate the claims to methods for treating acute otitis media from the claims to treatment of respiratory infections and to limit the respiratory infections to bacterial respiratory infections.

The pending claims are not being amended in response to any rejection under 35 USC 102(a) or under 35 USC 103(a).

No new matter has been added by this amendment.

The Examiner's rejections of objections and rejections of pending Claims 1-147 shall now be addressed in the order made by the Examiner.

Objection to the Abstract

The Examiner has objected to the abstract on the basis that the abstract's content fails to enable the reader thereof to quickly ascertain the character of the subject matter covered by the technical disclosure and fails to include that which is new in the art to which the invention pertains.

The Examiner reminded the Applicant of the 'proper content of an Abstract of the Disclosure' in stating that:

"In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use.... Exemplification of a species could be illustrative of members of the class. For processes, the type of reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

The Examiner concluded that complete revision of the content of the abstract is required.

The Examiner's objection to the abstract is not proper argument is incorrect as the present Application does not claim new compounds, compositions or new processes for making for making compounds. Rather, the present invention relates to a method for treating a bacterial infection comprising administering a single dose of azithromycin which is higher than that previously disclosed or suggested. In view of the actual invention, the present abstract properly reflects the present invention.

However, the Abstract is presently being amended to reflect the amendments presently made to the claims.

In view of the above, and of the amendment to the Abstract, the opposition is now moot.

#### Objection to the Claims

The Examiner has objected to Claims 30, 50, 70 and 130 under 37 CFR 1.75 as being substantially duplicative of Claim 20. The Examiner stated that Claims 20, 30, 50, 70 and 130 are drawn to treating acute otitis media comprising administering to a human a single dose of azithromycin of 30mg/kg body weight or more.

Contrary to the Examiner's statement, Claims 30, 50, 70 and 130 are not duplicative of Claim 20 as each of Claims 30, 50, 70 and 130 include an additional claim limitation not contained in Claim 20. Specifically, Claims 30, 50, 70 and 130 include the limitations that the acute otitis media was caused, respectively, by *S. pneumoniae*, an *S. pneumoniae* isolate containing a *mef A* gene, *H. influenzae* or *M. catarrhalis*.

#### Rejection of Claims 1-147

##### Under 35 USC 112, First Paragraph

The Examiner has rejected pending Claims 1-147 as not being enabling for treating all respiratory infections such as viral infections or fungal infections. However, the Examiner did state that the specification was enabling for the treatment of acute otitis media and for bacterial infections.

Responsive to the Examiner's statement that the specification was enabling for the treatment of acute otitis media and for bacterial infections, the pending claims have been amended to limit the said claims to the treatment of respiratory bacterial infections or to the treatment of acute media otitis.

Therefore, the Examiner's rejection is now moot.

Rejection of Claims 1-147

Under 35 USC 112, Second Paragraph

The Examiner has rejected pending Claims 20, 22, 30, 50, 70 and 130 under 35 USC 112, second paragraph, as being indefinite. Specifically, the Examiner has stated that these claims recite the treatment of acute otitis media but depend from claims reciting the treatment of respiratory infections, and that acute otitis media is not a respiratory infection.

Responsive to the Examiner's statement, Applicant's claims to the treatment of acute otitis media have been written to be independent of claims to the treatment of respiratory infections.

Therefore, the Examiner's rejection is now moot.

Rejection of Pending Claims Under 35 USC 102(a)

The Examiner has rejected Claims 1-2, 5-8, 20-23, 30-31, 34-37, 48, 50-51, 54-57, 68, 70-71, 74-77, 128, 130-131 and 134-137 under 35 USC 102(a) as being anticipated by the P/S/L Consulting Group reference. Also, the Examiner has rejected Claims 1-2, 5-8 and 20-23 under 35 USC 102(a) as being anticipated by the Block *et al.* reference.

The Examiner stated that P/S/L Consulting Group and Block *et al.* references disclose using a single-dose regimen, of 30mg/kg azithromycin, for treating children with acute otitis media. The Examiner has also presumed that a dose of about 35 mg/kg is anticipated by the teaching of a 30 mg/kg dose.

Therefore, the Examiner has concluded that Applicant's claims to a method of treatment using single doses of 35 mg/kg azithromycin are anticipated by the P/S/L Consulting Group and Block *et al.* references.

However, contrary to the Examiner's statement, the P/S/L Consulting Group and Block *et al.* references are not valid references under 35 USC 102(a) against the present Application. Specifically, the P/S/L Consulting Group and Block *et al.* references are publications of the results of a Pfizer Inc. clinical study. In fact, this Pfizer Inc. clinical study is included as an example, titled Single-Dose Azithromycin (30 mg/kg) in Acute Otitis Media, by Block *et al.*, in US Provisional Application 60/313,867, filed August 21, 2001, which the present Application claims the benefit of.

In addition, the Examiner has improperly assumed, without any cited basis, that a dose of about 35 mg/kg is anticipated by a purported prior art teaching of a dose of 30

mg/kg. On the contrary, it is clear from the present application that a dose of about 35 mg/kg is not equal to 30 mg/kg in that on Specification page 5, the recited preferred dose ranges are between about 30 mg/kg and about 35 mg/kg. Based upon the Examiner's interpretation, that the term about means  $\pm 5$  mg/kg, this preferred dose range nor the other cited dose ranges on Specification page 5 would be rendered insensible.

Therefore, in view of the above, the pending claims are not properly rejected, under 35 USC 102(a), as being anticipated by the P/S/L Consulting Group or Block *et al.* references.

Rejection of Claims 1-147 Under 35 USC 103(a)

The Examiner has rejected pending Claims 1-147 under 35 USC 103(a) as being obvious in view of the P/S/L Consulting Group reference in combination with Lazarevski *et al.* (US Patent No. 6,110,965). Specifically, the Examiner stated that the P/S/L Consulting Group reference discloses using a single-dose regimen, of 30mg/kg azithromycin, for treating children with acute otitis media. The Examiner also states the P/S/L Consulting Group reference discloses that acute otitis media is caused by *S. pneumonia*, *H. influenzae* and *M. catarrhalis*. The Examiner further states that Lazarevski *et al.* disclose that azithromycin is effective against various pathogens.

However, contrary to the Examiner's statement, the P/S/L Consulting Group and Block *et al.* reference is not a valid reference under 35 USC 103(a) against the present Application. Specifically, the P/S/L Consulting Group references is a publication of the results of a Pfizer Inc. clinical study which is included as an example, titled Single-Dose Azithromycin (30 mg/kg) in Acute Otitis Media, by Block *et al.*, in US Provisional Application 60/313,867, filed August 21, 2001, which the present Application claims the benefit of. Further, the subject matter, described in P/S/L Consulting Group, and the invention claimed in the present Application were commonly owned by Pfizer at the time the invention was made.

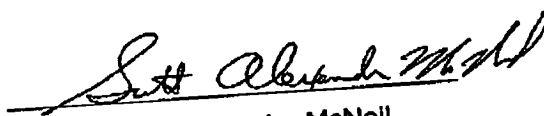
Conclusion

In view of the above, Applicant respectfully submits that the Examiner's rejections under 35 USC 112, first paragraph, 35 USC 112, second paragraph, USC 102(a) and 35 USC 103(a) of the pending claims, as amended, are not proper. Therefore, Applicant respectfully requests that these rejections of the pending claims, as

amended, be withdrawn. Further, Applicant respectfully requests that the objections to the Abstract and the pending claims be withdrawn. Applicant further requests that a notice of allowance be issued for the pending claims as presently amended.

Respectfully Submitted:

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